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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,915	06/27/2003	Stephen L. Hoffman	ABIOS.023A	7068

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EXAMINER	
WHALEY, PABLO S	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,915	HOFFMAN ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *85-108* is/are pending in the application.

4a) Of the above claim(s) *93-106* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *85-92,107 and 108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/27/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election without traverse of Group I drawn to Claims 85-92, 107 and 108, and election of Species I (iii), Species II (iii), and Species III (i) with traverse, filed 12/27/2005, is acknowledged. Applicants' arguments that the search of the complete invention claimed in Group I would not be burdensome has not been found to be persuasive, as the specie of "epitopes" are drawn to chemically distinct compounds as discussed in the previous office action. However, for efficiency of examination, the specie election requirement is withdrawn for Specie II and II. Applicants' arguments that Claim 108 is generic to the elected species has been found to be persuasive. Claims 93-106 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/27/2005.

CLAIMS UNDER EXAMINATION

Claims herein under examination are Claims 85-92, 107 and 108.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 85-92, 107 and 108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 85, 90, and 107 recite the limitation of determining an "affinity for the candidate peptide for said target protein." It is unclear if the applicant is referring to a "binding affinity" or to some other means of assessing the relationship between a protein and peptide (i.e. scoring). Clarification is requested. Claims 86-89, 91-92, and 108 are rejected as are dependent from Claims 85, 90, and 107.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 85-92, 107 and 108 are rejected under 35 U.S.C. 102 (b) as being anticipated by Parker et al. (Journal of Immunology, 1994, 152:163-175).

Parker et al. teach methods for predicting the relative binding strengths of all possible nonapeptides to the MHC class I molecule HLA-A2 (Abstract). More specifically, Parker et al. teach the following aspects of the instantly claimed invention:

- Obtaining experimental sequence and binding data for at least one peptide of known affinity for a target protein (Abstract)(Table I), as in instant claims 85, 90, and 107.
- Obtaining sequence data for a candidate peptide (β_2m) (Table I and II), as in instant claims 85 and 90 (line 5), and claim 107.
- A program which uses experimental binding and sequence data for peptides (p. 165, col. 1, lines 1-5 and Table 1), which correlates to a first predictive method as in instant claims 85 and 90 (lines 6-8, and claim 107.
- A second program used to optimize the output of the first program and further determines a maximum tolerable value (p. 164, col. 2, lines 45-51), which correlates to a second predictive method as in claims 85 and 90 (lines 9-13), and claim 107.
- Coefficients from the two programs are ranked and a table of values is created (p. 164, col. 2, lines 49-51), which correlates to combining and evaluating the data, as in instant claim 85 (lines 14-15), and claim 107.
- Ranking of experimental and theoretical data (Table VII), which correlates to obtaining a score reflecting the overall affinity as in instant claim 90 (line 15).
- Peptides comprising an amino acid (i.e. epitope) that binds to a MHC class I target protein (Abstact), as in instant claims 86, 91, and 108.
- Coefficients from programs were normalized to values between 0 and 1, and an overall normalization coefficient was determined (p. 164, col. 2, lines 16-19 and Table V), which

correlates to scaling the affinity as in instant claim 87, and normalization of data as in instant claim 90 (lines 13-14).

- Nonameric peptides were synthesized and coefficients were calculated for each of the nine positions for the (p. 164, col. 1, line 31, and col. 2, lines 16-22), which correlates to instant claim 88.
- Anchor scoring method (p.164, col. 1, lines 10-26), as in instant claims 89 and 92.

Claims 85, 86, 89, 107, and 108 are rejected under 35 U.S.C. 102 (b) as being anticipated by Altuvia et al. (J. Mol. Biol., 1995, 249, 244-250).

Altuvia et al. teach methods of ranking binding peptides to MHC molecules by a computational threading algorithm (Abstract). More specifically, Altuvia et al. teach the following aspects of the instantly claimed invention:

- Obtaining collection of sequences and binding data for at least one peptide of known affinity for a target protein (Abstract, Table 2, and p. 247, col. 2, lines 5-10), as in instant claims 85 and 107.
- Obtaining sequence data for peptides used in analysis (Table 1), which correlates to "candidate peptides" as in instant claims 85 and 107.
- Use of "simple sequence considerations" to predict binding between a peptide and target protein (p. 246, col. 2, paragraph 3), which correlates to a first prediction method as in instant claims 85 (lines 6-8) and 107.
- Use of peptide sequence data and interaction energy with MHC in the computation of binding potential via a "threading scheme" (p. 245, col. 2, lines 5-16), which correlates to a second prediction method as in instant claims 85 (lines 9-13) and 107.

- Combination of the two approaches (i.e. motif dependent and motif independent) to give the best results and rankings of peptides for binding affinity to MHC molecule (p. 247, col. 2, lines 54-58, and Table 4), as in instant claims 85 (lines 14-15) and 107.
- Prediction of peptides that bind to a given MHC molecule typically consist of 8 to 10 amino acids (p. 244, col. 1, lines 8-14), as in instant claims 86 and 108.
- Motif pattern scoring for prediction of potential binding peptides based on structure (p. 247, col. 2, lines 28-30 and Table 4), which correlates to a profile-based scoring method as in instant claim 89.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 85, 86, 89, 107 are rejected under 35 U.S.C. 103(a) as being obvious by Rammensee et al. (Immunogenetics, 1999, 50: 213-219), in view of Altuvia et al. (J. Mol. Biol., 1995, 249, 244-250).

Rammensee et al. teach a database for MHC ligands and peptides motifs (Abstract). More specifically, Rammensee et al. teach the following aspects of the instantly claimed invention:

- Obtaining collection of sequences and binding data for at least one peptide of known affinity for a target protein (Abstract), as in instant claims 85 and 107.
- Obtaining sequence data for peptides used in analysis (Table 1), which correlates to "candidate peptides" as in instant claims 85 and 107.
- An algorithm for epitope prediction of binding to MHC class I proteins using peptide sequence data (p. 214, col. 2, paragraph 2), which correlates to a first prediction method as in instant claims 85 (lines 6-8) and 107.
- Motif pattern scoring for prediction of potential binding peptides to MHC Class I proteins (Table 1), which correlates to a combining and evaluating data using a profile-based scoring method as in instant claim 85 (lines 14-15), 86, 89, and 107.

Rammensee et al. do not specifically teach the limitation of "a second predictive method" based on sequence and binding strength data, but do suggest the use of binding strength data (p. 217, col. 2, lines 12-18).

Altuvia et al., as previously discussed, teach a "threading scheme" for the prediction of peptide-protein (MHC class I) binding that incorporates peptide sequence data and interaction energy with MHC Class I molecules (p. 245, col. 2, lines 5-16).

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the invention of Rammensee et al. with the use of the "threading scheme" of Altuvia et al., where the motivation would have been to develop a more accurate predictive tool by incorporating both sequence and interaction energy data as taught by Altuvia

et al. (p.246, col.2, lines 1-7), resulting in the practice of the instant claimed invention with a reasonable expectation of success.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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2/6/06